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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,328	04/12/2001	Bernhard Laemmle	R-247.00CIP	3484

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EXAMINER
WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
1652	15

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/833,328	LAEMMLE ET AL.	
	Examiner	Art Unit	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *27,28 and 32-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The Response to Restriction Requirement filed on February 24, 2003, as paper No. 14, is acknowledged. Claims 1-35 are pending in the application; claims 1-26, 29 and 30-31 are the subject of this Office Action. Claims 27-28 and 32-35 are withdrawn from further consideration by the examiner as being drawn to a non-elected invention; see 37 CFR 1.142(b).

DETAILED ACTION

1. Election/Restriction

Applicant's election of Group I in Paper No. 14 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Group I comprises claims 1-26, 29 and 30-31, drawn to polypeptide having vWF protease activity, as well as to its composition; classified in class 435, subclass 219.

2. Priority

The application is a continuation-in-part of the US application No. 09/721,254, filed on November 11, 2000.

3. Objections

3.1. Specification

Line 8 on page 12 contains unnecessary word "this". The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors in the specification of which applicant may become aware.

3.2. Claims

Claims 29 and 31 are objected to as not complying with the sequence rules. The claims should contain the sequence identification number of the sequence toward which they are directed.

4. Rejections

4.1. 35 USC section 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 18 recites the limitation "an isolated polypeptide according to claim 14". There is insufficient antecedent basis for this limitation because claim 14 is not directed to a polypeptide.

Claim 29 being dependent on claim 18 is included in this rejection, because it does not correct the language of the base claim.

4.2. 35 USC section 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-26, and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Furlan et al. (Partial Purification and Characterization of a Protease from Human Plasma Cleaving von Willebrand Factor to Fragments Produced by *in Vivo* Proteolysis, Blood, 1996, 87/10, 4223-4234; copy enclosed).

The claims are directed to a composition exhibiting von Willebrand factor (vwF) protease activity wherein said composition:

(1) comprises at least one single peptide chain having a molecular weight between 190 and 100 kD, i.e., 180 kD, 170 kD, 160 kDa, 120 kD, 110 kD, wherein said chain comprises the amino acid sequence of SEQ ID NO: 1 or amino acid sequence of SEQ ID NO: 1 followed

immediately by the amino acid sequence of SEQ ID NO: 15 or of SEQ ID NO: 4,

(2) cleaves vWF at the peptide bond 842Tyr-843Met,

(4) retains activity in the presence of a serine protease inhibitor (diisopropyl fluorophosphate) and a calpain protease inhibitor (Z-Leu-Leu-Tyr-CHN_2), and

(5) comprises Ca^{2+}, Sr^{2+} or Ba^{2+} ions; and

(6) wherein the amino acid sequence consisting of SEQ ID NO: 1 followed by SEQ ID NO: 15, or amino acid sequence of SEQ ID NO: 4, are encoded by the nucleotide sequence presented in Fig. 2 of the specification.

Furlan et al. disclose a composition obtained (Fig. 6 and 7, page 4228) from human plasma, wherein said composition has the activity of vWF protease (page 4227, left column starting from the subtitle *Purification of the protease*) with cleavage site between 842Tyr-843Met (page 4230 left column starting from the subtitlte *Amino acid analysis and amino acid sequence of vWF and its degradation products*), wherein the composition is not inhibited by protease inhibitors (page 4229 left column, starting from the subtitle *Effect of protease inhibitors on vWF degradation*) such as the serine protease inhibitor diisopropyl fluorophosphates (page 4229, right column, line 6) and the calpain protease inhibitor Z-Leu-Leu-Tyr-CHN_2 (page 4229, right column, line 13) and wherein the composition is the most active in the presence of Ca^{2+}, Sr^{2+} or Ba^{2+}

ions (page 4228, right column, starting with the subtitle *Activation by metal ions and pH optimum of the vWF cleavage protease*).

Furlan et al do not particularly teach that the composition contains peptide chains that are between 190 and 100 kD, i.e., 180 kD, 170 kD, 160 kD, 120kD, 110 kD, however one skilled in the art can recognize in Fig. 7 of the article the bands corresponding to the enumerated molecular weights. These bands are presented together with their molecular weights in Table 1 of the specification.

Furlan et al. do not teach the polypeptide whose N-terminal comprises SEQ ID NO: 1 or SEQ ID NO: 4 or SEQ ID NO: 1 immediately followed by SEQ ID NO: 15, or the polypeptide whose N terminus is SEQ ID NO: 4. However, SEQ ID NO: 1, and 4 and 15 are inherent features of the C-terminal truncated forms of the very vWF protease that is disclosed by Furlan at al. and are inheritently encoded by the DNA of Fig. 2.

Although Furlan et al. do not particularly teach that the composition contains peptide chains that comprise amino acid of SEQ ID NO: 1 or amino acid sequence of SEQ ID NO: 1 followed immediately by the amino acid sequence of SEQ ID NO: 15 or amino acid of SEQ ID NO: 4, Table 2 of the specification, as well as Table 2 of the paper by Gerritsen et al. (Partial amino acid sequence of purified von Willebrand factor-cleaving perotease, Blood, 2001, 98, 1654-1661) clearly show that each of the bands of molecular weights 150 kD, 140 kD, 130 kD, 110 kd unreduced, and 180 kD, 170 kD, 169 kD and 120 kD reduced do have the recited N-terminal that starts with SEQ ID NO:1 or SEQ ID NO: 1 immediately followed by SEQ ID NO:15, when long enough streches of the N- terminal part of the protein were sequenced. The paper by Gerritsen

et al. shows that characteristics not disclosed in the reference by Furlan et al. is inherent; see MPEP 2131.01 "Multiple Reference in 35 U. S.C. 102 Rejections [R-1] (C).

Since the Office does not have the facilities for examining and comparing Applicants' protein with the protein of the prior art, the burden is on Applicants to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

5. Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.
Patent Examiner
Art Unit 1652

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1900~~ 1600